

**Summary of the
Accrediting Authority Committee Teleconference
December 4, 1996**

The National Environmental Laboratory Accreditation Conference's (NELAC's) Accrediting Authority Committee met by teleconference from 1:00 to 3:00 p.m. Eastern Standard Time (EST) on Wednesday, December 4, 1996. The meeting was led by the Committee chair, Mr. John Anderson of the State of Illinois Environmental Protection Agency (IL-EPA). A list of action items is given in Attachment A. A list of Committee members/invited guests is given in Attachment B. A copy of the teleconference agenda is given in Attachment C.

INTRODUCTION

The purpose of the teleconference was to continue to discuss the updated version of Chapter 6.
The following items were discussed:

- Action Items Identified in the Minutes of the November 26, 1996, Teleconference -- Minutes had been prepared and reviewed by Mr. Anderson but had not been approved by Ms. Jeanne Mourrain, NELAC Director, so they were not distributed to the Committee at this meeting.
- Review of the Updated Version (Revision 4) of Chapter 6 -- The Committee systematically reviewed section by section the current draft of Chapter 6.

The Committee discussed the Second NELAC Interim Meeting to be held at the Bethesda Hyatt Regency (301) 657-1234, Bethesda, MD, February 3-5, 1996. The Environmental Laboratory Advisory Board (ELAB) meeting is scheduled for February 6, 1996. The Third NELAC Annual Meeting will be held at the Wyndham Anatole Hotel in Dallas, TX, July 28-31, 1997.

The issue of an accrediting authority's accrediting its own laboratory was raised. Currently, the IL-EPA accredits other agencies, but not its own laboratories. Mr. Anderson will discuss this issue with Ms. Mourrain.

REVIEW OF ACTION ITEMS IN MINUTES OF NOVEMBER 26, 1996, TELECONFERENCE

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| Item 1. | Completed. | Mr. Jack Farrell rewrote Section 6.3.3(d)(13). The revision was included in Revision 4 of Chapter 6 and was distributed to Committee members. |
| Item 2. | Completed. | Mr. Anderson rewrote Section 6.3.3(d)(17) to reflect a requirement that an accrediting authority maintain records for a minimum of 10 years. |

Item 3. Completed. Mr. Anderson and Ms. Jeri Long rewrote Section 6.3.3(d)(19)(C) to clarify conflict-of-interest issues for subcontractors.

SYSTEMATIC REVIEW OF CHAPTER 6

6.3.3 -- Application Technical Review by a NELAP Assessment Team

(d)(10)(C)

The Committee approved this section as written, noting that this section gives an accrediting authority support for revoking a laboratory's accreditation if the laboratory misrepresents its accreditation status for a particular field of testing. The Committee noted that Chapter 4 deals specifically with enforcement issues and mechanisms.

(d)(11)

The Committee approved the deletion of the terms "suspension, voluntary surrender, or expiration."

(d)(11)(A)

The Committee approved the addition of "past NELAP" accreditation.

(d)(13)

The Committee agreed that Mr. Farrell's revision of this section was acceptable, but it raised questions about enforcement issues, such as the withholding of National Environmental Laboratory Accreditation Program (NELAP) recognition on the basis of poor performance on an internal audit. The Committee agreed that the NELAP assessment team would not only identify elements of the organization that were out of compliance, but would also recommend corrective action. The lack of specificity of the term "effectiveness" was also discussed, since the objectives of internal audits differ from State to State. The Committee agreed that this section should be modified to include the same terminology used in the previous revision: "has a documented procedure in place to conduct systematic internal audits of the entire accrediting authority's

quality system, at least annually, to verify the effectiveness of the quality systems and compliance with the NELAC standards. Where appropriate, the audit should follow the same policies and procedures for internal audits used by all other programs, units, divisions, bureaus, etc. in the department or agency in which the accrediting authority is located.”

(d)(17)

The Committee discussed the designation of a minimum 10-year time period for record retention. A suggestion was made that an 8- or 12-year period might be more appropriate because these periods are consistent with the 4-year cycle for NELAP recognition and renewal. Currently, the State of North Carolina is required to keep records on-site for five years and in archives for five years. The State of Kansas keeps records for three years on-site. The National Lead Laboratory Accreditation Program (NLLAP) requires that records be maintained for 10 years. The Committee agreed to maintain the 10-year time period for record retention as written in this section. In addition the Committee agreed that the archival location was to be selected by the accrediting authority (no requirement for on-site maintenance) and that records could be retained either on paper or electronically.

(d)(19)(C)

The Committee discussed the meaning of direct and indirect involvement in laboratory organizations. Section ii was discussed extensively because the Committee considered that precluding a subcontractor’s employees, or the auditor of an accrediting authority, from belonging to a professional laboratory organization would be difficult. A suggestion was made to refer to ISO Guide 58, which addresses this conflict-of-interest issue from the standpoint of impartiality. Impartiality was clearly stated in Section iii. A suggestion was made to revise the section to read: “ensure that the subcontractor or his employees are not directly involved with:” The Committee agreed to delete Section ii and to review the entirety of Chapter 6 to ensure that references to subcontractors are included in sections that address conflict-of-interest issues.

(d)(21)(A)

The Committee approved this section as written, adding “the” manager.

(d)(21)(D)

Changes in this section were editorial. The Committee approved the revision.

(e)

The Committee agreed with the revision of this section, clarifying the status of an accrediting authority’s recognition (interim versus “final”) by adding “initial” application. (Recognition is awarded upon satisfactory completion of an on-site audit.) Because this section did not address renewal of accreditation, which is also contingent upon satisfactory completion of an on-site audit, Mr. Anderson will either rewrite this section to address renewal issues or add a section specifically addressing the renewal process.

(f) and (g)

Changes in these sections were editorial and were approved.

(g)(4)(A) and (B)

The Committee discussed the appropriateness of the terms, “promulgate” and “seek.” The use of “seek” was interpreted to require more time than “promulgate;” therefore, “seek” was considered to be applicable to the legislative process rather than to the regulatory process. The Committee considered that the time allowed for extension (two years) was adequate for correcting deficiencies in the accrediting authority’s application. In North Carolina, the legislative process can be facilitated in one year because laboratory accreditation programs are self-supporting. An extension of two years may be granted to an accrediting authority at the discretion of the NELAC Director. The Committee agreed to maintain the sections as written but to examine the differences in time requirements for regulatory and legislative processes at the NELAC Interim Meeting.

(g)(6)

This section was included for informational purposes only. A suggestion was made to remove the reference to the “two year time requirement” and to allow the accrediting authority to specify a time frame for making corrections, since legislative time requirements differ from State to State. In New York, for example, there are income considerations and the legislative process may require more time than in North Carolina, where there are no funding constraints. A suggestion was made to keep the reference to two years as a way of limiting the time frame for the legislative/regulatory process without impeding the application-correction process for non-regulatory and non-legislative issues in an accrediting authority’s application for NELAP recognition. However, the Committee agreed that the accrediting authority would not have control over the time required for legislation. This issue will be added for discussion at the NELAC Interim Meeting.

(h)

The Committee concurred that this section did not address both initial accreditation and renewal, and suggested that two sections be written to address both issues because an on-site audit is required only once every four years for renewal, since renewal in the “no audit required” years is contingent only upon satisfactory review of the renewal application. The question of unsatisfactory completion of an on-site audit during the renewal process was raised in light of the potential loss of recognition or change to interim recognition. The Committee concurred that emphasis should be given to correcting the deficiency. Changing the status from “recognition” to “interim recognition” would open up another level of bureaucratic processes for the accrediting authority. Mr. Anderson and Ms. Long will rewrite this section to address the change in recognition status during the renewal process, and the Committee will discuss this section at the next teleconference.

(j)

The four-year cycle for submitting an application, completing an on-site audit, and renewing an application through satisfactory completion of an on-site audit will be incorporated into this section.

Section 6.4 -- On-Site Audit of the Accrediting Authority

(b)

The Committee considered the effectiveness of including unannounced audits and agreed to remove “routine” and rewrite this section as follows: “The NELAP assessment team will arrange on-site audits.”

(c)

The Committee considered that the accrediting authority must be in compliance with all NELAC standards rather than the requirements of Chapter 6 and agreed to change “this Chapter” to “NELAC standards.”

Section 6.4.1 -- Scheduling of Initial or Routine On-Site Audits

The Committee agreed to delete the terms “Initial or Routine” consistent with Section 6.4(b).

(a)

The Committee concurred that terminology should be added to be consistent with the initial application or the four-year renewal application. This section was rewritten as follows: “The NELAP assessment team shall contact the accrediting authority within 15 days of the approval date of the NELAP-recognition application to schedule the on-site audit as set forth in Section 6.4(a) above.”

6.4.2 -- Conducting the On-Site Audit

(a)

The Committee agreed that to maintain consistency with Section 6.4(c) terminology in this section should reflect the requirements of the “NELAC standards,” and rewrote the section as follows: “The purpose of the on-site audit is to verify compliance with the NELAC standards, including, but not limited to:”

(d) and (e)

The Committee raised the question of the NELAP assessment team’s rights to 1) talk with personnel in a laboratory accredited by the accrediting authority, and 2) to observe day-to-day activities of the accrediting authority. Mr. Anderson indicated that Ms. Mourrain, NELAC Director, and Dr. Charles Hartwig, Chairman of the NELAC Board of Directors, were opposed to requiring that the assessment team observe activities of the accrediting authorities (such as auditing a laboratory) because of resource limitations. The Committee concurred that the objective of international acceptance of NELAP will only be achieved if NELAP complies with ISO Guide 58. Section 5.2 of ISO Guide 58 addresses an accrediting authority’s requirement to

monitor the performance of assessors, which may or may not be applicable to the right of the NELAP assessment team to observe an accrediting authority perform an on-site audit of a laboratory. In order to address limitations in the on-site audit, Mr. Farrell and Mr. Anderson will review ISO Guide 58, and Mr. Anderson will add language to Section (d) to allow the assessment team the right to talk to personnel in a laboratory accredited by the accrediting authority.

Section 6.4.3 -- On-Site Audit Reports

(a)(3)

In order to be consistent with terminology used in Chapter 2, “Proficiency Testing,” the Committee agreed to change the term “scope” to “field of testing.” Field of testing is defined as analyte/matrix/regulatory program, but does not address analytical method.

(a)(4)

In order to be consistent with Section 6.4(c), the Committee agreed to revise this section to read “NELAC standards” rather than “requirements of this Chapter.”

(c)(2)

The Committee agreed to delete “or this Chapter” and change “standard” to the plural form, “standards.”

(d)(4)

The Committee discussed this section and concurred that the NELAP assessment team can suggest an appropriate extension of time to correct on-site audit deficiencies, but the accrediting authority must make a formal request to the NELAC Director for the time extension.

(d)(5)

This section addresses interim recognition (granted after a satisfactory completion of the paper audit) only, and will be rewritten to address renewal of recognition. The term “full” recognition implies all fields of testing and is not appropriate in the context of this section.

(e)

The Committee suggested that the NELAP assessment team shall recommend revocation of NELAP recognition within 30 days of an on-site audit if an accrediting authority fails to submit a plan for corrective action. This section will be rewritten to address the 30-day time requirement.

(f)

The Committee agreed that after the NELAP assessment reviews an accrediting authority’s plan for corrective action to determine if any deficiencies were not addressed, the team would make recommendations to the NELAP Director. An addition will be made to this section to indicate that correspondence delineating the deficiencies and their corrective action(s) will be sent to all parties.

(h)

This section addressed a funding issue that had not been clearly defined. Therefore, the Committee extensively discussed its interpretations in an effort to unambiguously state a position. Questions about the sources and availability of funding for on-site auditing and recognition of an accrediting authority were raised. Funding requirements for on-site audits were estimated. (Committee members estimated that, based on a four-year audit cycle, a maximum of \$15,000 per person per year would be required for travel/accommodations for on-site audits.) After a lengthy discussion, the Committee agreed that, because NELAP will be an EPA-directed program, the EPA should provide resources for travel/accommodations for NELAP assessment teams to perform on-site audits of an accrediting authority. Mr. Anderson will discuss this issue with Ms. Mourrain, and he will write a letter to the Board of Directors for clarification.

(i)

The Committee approved with this section as written.

Section 6.5 -- NELAP Assessment Team Recommendations to the NELAP Director

The Committee approved the revision of this section.

Section 6.6 -- Certificate of Recognition to the Accrediting Authority

(a)

The Committee agreed that the term “interim” should be deleted because “interim” refers only to recognition granted after the paper (application) review.

(b)(4)

The Committee concurred that the wording “either interim or renewal” should be deleted and that this section should be revised as follows: “the expiration date of the accrediting authority’s NELAP recognition which shall not be more than two years from the date of the most recent date granting NELAP recognition.”

(b)(5)

The Committee agreed to use the plural form of “signature” and to revise the section as follows: “the signatures of the NELAP assessment team members.”

(b)(10)

The Committee agreed that, because a seal has a legal bearing, each NELAP certificate should bear a seal with the NELAP insignia. This section will be rewritten to include an addition indicating that each certificate of NELAP recognition will be designated by a seal bearing the NELAP insignia.

Section 6.7 -- Requirements of NELAP

(b)

The Committee agreed that the time period for record retention, “a minimum of ten years,” will be added to this section to be consistent with Section 6.3.3(d)(17).

Section 6.7.1 -- NELAP Assessment Team

(b)

Mr. Anderson reviewed with the Committee his discussions with Ms. Mourrain, NELAC Director, in which the NELAP assessment team was projected to be comprised of two members -- one from the USEPA and the second from a state (accrediting authority).

(c)

The Committee agreed that the term “No later” should be added so that this section reads as follows: “No later than two years from the date . . .”

(f)

The Committee agreed that Section (f) should be added to indicate that NELAP should encourage maintaining the same assessment team be for the four-year cycle, consistent with Section 6.3.3(a)(4).

CONCLUSION

Mr. Anderson concluded the teleconference by indicating that revisions would be made in the existing document and that Revision 5 of Chapter 6 would be sent to the Committee for review before the next teleconference. In addition, the comments of Ms. Aurora Shields regarding “unconditional” reciprocity in Section 6.2(c) will be distributed to the Committee. This issue will be discussed at the next teleconference.

NEXT TELECONFERENCE

The next teleconference is scheduled for Tuesday, December 10, 1996, from 1:00 to 4:00 p.m EST.

ACTION ITEMS
Accrediting Authority Committee Teleconference
December 4, 1996

Item No.	Action	Date Completed
1	Mr. Anderson will discuss the process of an accrediting authority's accrediting its own laboratory.	
2	Mr. Anderson will merge Section 6.3.3(d)(13) in Revisions 3 and 4 to incorporate Committee discussions and finalize a new Section 6.3.3(d)(13) for Revision 5.	December 6, 1996
3	Mr. Anderson will delete Section 6.3.3(d)(19)(C)ii to be consistent with the consensus of the Committee that a subcontractor can participate in activities associated with professional laboratory organizations.	December 6, 1996
4	Mr. Anderson will rewrite Section 6.3.3(e) to address issues associated with the renewal of an accrediting authority's NELAP recognition.	December 6, 1996
5	The Committee considered that the time frame allowed to an accrediting authority for correcting deficiencies in its accreditation program that require regulatory or legislative changes should be discussed at the NELAC Interim Meeting. Mr. Anderson will add this item to the agenda for that meeting.	December 6, 1996
6	Mr. Anderson and Ms. Long will revise Section 6.3.3(h) to address renewal of NELAP recognition, and changes in the status of NELAP recognition if the accrediting authority performs poorly on the on-site audit for renewal of recognition.	December 6, 1996
7	Mr. Anderson and Ms. Long will revise Section 6.3.3(j) to address the four-year cycle of NELAP recognition and renewal of recognition.	December 6, 1996
8	Mr. Anderson will rewrite Section 6.4(b) to delete "routine" on-site audits.	December 6, 1996

ACTION ITEMS
Accrediting Authority Committee Teleconference
December 4, 1996

Item No.	Action	Date Completed
9	Mr. Anderson will rewrite Section 6.4(c) to indicate that requirements of NELAC standards, rather than Chapter 6, will be met.	December 6, 1996
10	Mr. Anderson will delete "Initial or Routine" from the title of Section 6.4.1.	December 6, 1996
11	Mr. Anderson will review ISO Guide 58 for clarification of the rights of the NELAP assessment team to observe the accrediting authority carrying out an on-site audit. Dr. Jeff Flowers will talk with Ms. Roxanne Robinson for additional information about ISO Guide 58 requirements for observation of on-site audits. Mr. Anderson will add Section 6.4.2(a)(3) to address this issue.	December 6, 1996
12	Mr. Anderson will revise Section 6.4.2(e) to include the right of the NELAP assessment team to talk with personnel in a laboratory accredited by the accrediting authority undergoing an on-site audit.	December 6, 1996
13	Mr. Anderson will rewrite Section 6.4.3(a)(3) to change "scope" to "field of testing" to be consistent with NELAC terminology.	December 6, 1996
14	Mr. Anderson will rewrite Section 6.4.3(a)(4) to indicate that requirements of NELAC standards, rather than Chapter 6, will be met.	December 6, 1996
15	Mr. Anderson will rewrite Section 6.4.3(c)(2) to indicate that NELAC standards will be met.	December 6, 1996
16	Mr. Anderson will rewrite Section 6.4.3(d)(5) to include the renewal of NELAP recognition.	December 6, 1996
17	Mr. Anderson will rewrite Section 6.4.3(e) to include the 30-day requirement for notifying NELAP of an accrediting authority's plan for corrective action.	December 6, 1996

ACTION ITEMS
Accrediting Authority Committee Teleconference
December 4, 1996

Item No.	Action	Date Completed
18	Mr. Anderson will rewrite Section 6.4.3(f) to indicate that the NELAP assessment team's correspondence regarding uncorrected deficiencies will be sent to all parties.	December 6, 1996
19	Mr. Anderson will discuss the issue of funding (travel/accommodations) for on-site audits with Ms. Mourrain, and he will write a letter to the NELAC Board of Directors for clarification.	December 6, 1996
20	Mr. Anderson will rewrite Section 6.6(a) deleting references to "interim" NELAP recognition.	December 6, 1996
21	Mr. Anderson will rewrite Section 6.6(b)(4) to delete references to interim or renewal recognition.	December 6, 1996
22	Mr. Anderson will rewrite Section 6.6(b)(5) to pluralize the word "signature."	December 6, 1996
23	Mr. Anderson will add Section 6.6(b)(10) to indicate that a seal bearing the NELAP insignia will be affixed to each certificate of recognition.	December 6, 1996
24	Mr. Anderson will rewrite Section 6.7 (b) to include the requirement that records be maintained for a minimum of 10 years.	December 6, 1996
25	Mr. Anderson will rewrite Section 6.7.1(c) to indicate that no later than two years after the NELAP program has been implemented, one member of the NELAP assessment team will be from a NELAP-recognized accrediting authority.	December 6, 1996
26	Mr. Anderson will add Section 6.7.1(f) to indicate that NELAP will encourage the same NELAP assessment team to be maintained for the four-year cycle of recognition and renewal.	Already in Section 6.3.3(a)

LIST OF COMMITTEE/TELECONFERENCE PARTICIPANTS
Accrediting Authority Committee Teleconference
December 4, 1996

Name	Affiliation	Phone/Fax/E-mail
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AGENDA
Accrediting Authority Committee Teleconference
December 4, 1996

Wednesday, December 4, 1996
1:00 - 3:00 p.m. Eastern Standard Time

Review minutes of 11/26/96
Committee Meeting and Status of
Assignments from that meeting
(Minutes not yet distributed).

Discuss and hopefully approve wording
changes authorized during our 11/26/96
meeting. These wording changes are
shown as strike-outs and underlines in
Sections 6.0 - 6.3.3(d)(19)(C) on pages
1-22 of Chapter 6, Revision 4,
dated 11/26/96.

Continue systematic review of Chapter 6, Section
by Section, starting at 6.3.3(d)(20) on page 22 of the
double-spaced Revision 4 of Chapter 6 dated
11/26/96.

2:45 p.m.

- Assess progress made at today's meeting.
- How to proceed from here.
- Assignments for interim between now and
next meeting.

3:00 p.m. - Automatic Shutoff.